DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 26, 2014

Covidien LLC
Mr. Michael Koczocik
Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K143091
Trade/Device Name: Surgisleeve™ Wound Protector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, KKX
Dated: October 27, 2014
Received: October 28, 2014

Dear Mr. Koczocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143091

Device Name

Surgisleeve™ Wound Protector

Indications for Use *(Describe)*

The Surgisleeve™ Wound Protector is indicated for use to access the abdominal cavity during surgery through an atraumatically retracted incision, deliver maximum exposure of the abdominal cavity with minimum incision size, and protect against wound contamination during laparoscopic and open surgery. Additionally, the small size Wound Protector is indicated for use to access the thoracic cavity during cardiac and general surgical procedures through an atraumatically retracted incision. The extra-small Wound Protector is also indicated for use to access the thoracic cavity and other soft tissue retraction during cardiac and general surgical procedures through an atraumatically retracted incision.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary of data used to demonstrate substantial equivalence is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98

NAME:	COVIDIEN
ADDRESS:	60 Middletown Avenue North Haven, Connecticut 06473 USA
CONTACT PERSON:	Michael Koczocik Product Specialist, Regulatory Affairs
PHONE NUMBER:	(203) 492-6312
FAX NUMBER:	(203) 492-5029
DATE PREPARRED:	October 27, 2014
TRADE/PROPRIETARY NAME:	Surgisleeve™
COMMON/USUAL NAME:	Wound Protector
CLASSIFICATION NAME:	Endoscope and Accessories per 21 CFR § 876.1500 Surgical Drape and Drape Accessories per 21 CFR § 878.4370
PRODUCT CODE:	GCJ, KKX
CLASSIFICATION PANEL NAME:	Gastroenterology and Urology General and Plastic Surgery,
FDA PANEL NUMBER:	78, 79
DEVICE CLASS:	Pursuant to 21 CFR § 876.1500 and 21 CFR § 878.4370 an endoscope and accessories/surgical drape is a Class II device
PREDICATE DEVICE(S):	Surgisleeve™ Wound Protector K140064
DEVICE DESCRIPTION:	Wound retraction device providing thoracic and abdominal access and protection from wound contamination

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INTENDED USE:	The Surgisleeve™ Wound Protector is indicated for use to access the abdominal cavity during surgery through an atraumatically retracted incision, deliver maximum exposure of the abdominal cavity with minimum incision size, and protect against wound contamination during laparoscopic and open surgery. Additionally, the small size Wound Protector is indicated for use to access the thoracic cavity during cardiac and general surgical procedures through an atraumatically retracted incision. The extra-small Wound Protector is also indicated for use to access the thoracic cavity and other soft tissue retraction during cardiac and general surgical procedures through an atraumatically retracted incision.
SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED AND PREDICATE DEVICE(S)	The Surgisleeve™ Wound Protector's Cylindrical Film is designed to retract an incision and provide protection from wound contamination. The interior and exterior rings are flexible to aid insertion, film retraction, and removal. The technological characteristics of the extra-large Surgisleeve™ remain the same as the 510(k) cleared Surgisleeve™ device (K140014). The retraction ring of the large and extra-large Surgisleeve™ Wound Protector is a rigid circular ring accessory that attaches to the exterior ring that aids in maintaining maximum retraction for both the large and extra-large device when necessary
MATERIALS:	All components of the Surgisleeve™ Wound Protector are comprised of materials which are in accordance with ISO 10993-1

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PERFORMANCE DATA:

In-vitro and in-vivo tests were performed to verify that the performance of the Surgisleeve™ Wound Protector with Retraction Ring is substantially equivalent to the predicate devices. To validate that the proposed device performs as intended to provide access into the body cavity and maintain maximum retraction, the following tests were performed:

- In-vitro proximal ring rolling
- In-vitro strength of attachment between film and proximal (exterior) and distal (interior) rings
- In-vitro film weld strength
- In-vitro retraction ring compression force
- In-vivo digital proximal ring insertion
- In-vivo proximal ring rolling
- In-vivo retraction ring insertion and removal
- In-vivo digital distal ring removal

CONCLUSION:

The results of the performance evaluation demonstrate that the Surgisleeve™ Wound Protector extra-large with Retraction ring performed substantially equivalent to the predicate device, Surgisleeve™ Wound Protector K140064.